UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

VICTORIA CLEMENTS, **Plaintiff,** **v.** **SANOFI-AVENTIS, U.S., INC., AVENTIS PHARMACEUTICALS, INC., and JOHN DOE A to Z, individually, jointly, and/or severally,** **Defendants.**	Civ. No. 14-cv-1423 (KM) **OPINION**

KEVIN MCNULTY, U.S.D.J.:

This is a personal injury action brought by plaintiff Victoria Clements for injuries allegedly sustained following the administration of Sculptra, a medical device consisting of an injectable substance intended to treat the loss of facial fat. Now before the Court is the motion of the defendants (collectively, "Sanofi") for summary judgment. For the reasons set forth below, the motion is denied as presented, but granted to the extent that the complaint is dismissed without prejudice.

Sanofi has styled its motion as one for summary judgment under Federal Rule of Civil Procedure 56. Plaintiff Clements has not submitted a responsive Statement of Material Facts Not in Dispute, as required by Local Rule 56.1(a). Nor has Clements really made any substantial factual showing in opposition to Sanofi's summary judgment motion. Clements's explanation is that she has not had the opportunity to complete discovery, and that Sanofi's summary judgment motion is therefore premature.

If Clements's explanation were properly presented, and if I accepted it, I might simply terminate Sanofi's motion and permit discovery to proceed.

Sanofi's contentions, however, are arguments of law. For example, Sanofi argues that the state law causes of action pled in the complaint are either preempted by federal law or subsumed by the New Jersey Products Liability Act. Such contentions, directed to the face of the complaint, are appropriate for consideration under the standards for a Rule 12(b)(6) motion to dismiss. The only extrinsic facts relevant to such a motion pertain to the FDA approvals of Sanofi's medical device. Those approvals are admitted by the plaintiff in her brief, and in any event are readily susceptible of judicial notice. *See* p. 4 n.2, *infra.* I also observe that Clements's complaint is not pleaded with the factual specificity required by the Federal Rules. I therefore may profitably treat this as the equivalent of a motion to dismiss.[1]

The complaint as presented should be dismissed. I conclude, however, that neither summary judgment nor a dismissal with prejudice would be procedurally fair. This state-law complaint was removed from state court to federal court by Sanofi. When Clements filed it, she was not reasonably on notice that she would be held to federal pleading standards. Her brief in opposition to Sanofi's motion also asserts facts, not pled in the complaint, that she says would support a non-preempted claim. I do not rule on those contentions in advance. I do, however, provide that this order of dismissal is without prejudice to the filing of an amended complaint within 30 days.

I. BACKGROUND

Statutory Background

Congress passed the Medical Device Amendments (MDA) to the FDCA in 1976 to impose uniform requirements for the introduction of new medical

[1] *See generally Dolan v. Nicoll,* 2005 WL 1657029 at *1 (D.N.J. July 13, 2005) ("Defendant [] filed a summary judgment motion, which this Court treats as a motion to dismiss"). Alternatively, I might assume *arguendo* that there are issues of fact and construe the facts in Clements's favor, but nevertheless consider whether Sanofi "is entitled to judgment as a matter of law" under Rule 56(a). Either way, there are potentially dispositive issues of law that are appropriate for consideration now.

devices into the market. *See* 21 U.S.C. § 301 *et seq.* The MDA established three levels of federal oversight depending on the risks presented by a particular medical device. The devices that receive the highest level of scrutiny are Class III medical devices: those "purported or represented to be for a use in supporting human life or for a use which is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury." 21 U.S.C. § 360(1)(c)(ii).

The MDA subjects Class III medical devices to a rigorous premarket approval ("PMA") process. The PMA process is designed to "provide reasonable assurance" of the device's safety and efficacy. 21 U.S.C. § 360(a)(C)(ii)(II). PMA review requires, among other things, the following:

> [F]ull reports of all studies and investigation of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a "full statement" of the device's "components, ingredients, and properties and of the principle or principles of operation"; "a full description of the methods used in, and the facilities and the facilities and controls used for, the manufacture, processing, and when, when relevant, packing and installation of, such device"; samples or device components required by the FDA; and a specimen of the proposed labeling.

Riegel v. Medtronic, Inc., 552 U.S. 312, 317 (2008) (quoting 21 U.S.C. § 360e(c)(1)). PMA review also requires the Food and Drug Administration ("FDA") to "determine that the [device's] proposed labeling is neither false nor misleading." *Id.* at 318 (quoting 21 U.S.C. § 360e(d)(1)(A)). A manufacturer cannot manufacture or sell a device unless it receives PMA. Once a device has been approved, "the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Id.* at 319.

FDA Approval of Sculptra[2]

Sculptra, a Class III medical device, was approved through the PMA process on August 3, 2004, after a nine-month review. (Def. Statement of Undisputed Facts Pursuant to Local Rule 56.1, Dkt. No. 9-1, ¶1) Sculptra was initially approved "for the restoration and/or correction of the signs of lipoatrophy—commonly known as facial fat loss—in people with human immunodeficiency virus ('HIV')". (*Id.*)

On July 28, 2006, Sanofi filed a supplemental PMA application to allow Sculptra to be used for cosmetic purposes, regardless of whether its recipients suffered from HIV. (*Id.* at ¶2)

On July 28, 2009, after a three-year review, the FDA granted PMA, approving Sculptra's use in "immune competent people as a single regimen for correction of shall to deep nasolabial fold contour deficiencies and other facial wrinkles in which deep dermal grip pattern injection technique is appropriate." (*Id.*) Although marketed under a different name— "Sculptra Aesthetic"—Sanofi states that the device is identical to Sculptra. (*Id.* at ¶5)

The FDA has never revoked, suspended, or otherwise interrupted its approval of Sculptra or Sculptra Aesthetic. (*Id.* at ¶4)

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[2] Clements, although she does not plead these facts about the regulatory process in her Complaint, relies on them in her brief. (*See* Dkt. No. 14, at 4-9)

These facts about the FDA approvals of Sculptra are also matters of public record, appropriate for judicial notice under Federal Rule of Evidence 201. *Desai v. Sorin CRM USA, Inc.*, 2013 WL 163298, at *4 (D.N.J. Jan. 15, 2013) (Walls, J.) (court "takes judicial notice of the FDA's website, and holds that it establishes premarket approval of the Biotronik lead" medical device); *see also Kos Pharmaceuticals, Inc. v. Andrx Corp.*, 369 F.3d 700, 705 n.5 (3d Cir. 2004) (taking judicial notice of PTO notice of allowance of trademark for drug); *Novartis Pharmaceuticals Corp. v. Wockhardt*, 2013 WL 5770539, at *4 (D.N.J. Oct. 23, 2013) (Wigenton, J.) (taking judicial notice of Novartis's citizen petition to block approval of generic drug and of the FDA's response).

Clements's Use of Sculptra

The facts in this section are not contained in the Complaint. I refer to them as background, and also because they are relevant to my decision that the dismissal of the complaint should be without prejudice.

According to Clements's brief, in 2004 Sculptra was approved for use on HIV/AIDS patients. (Dkt. No. 14 at 5) She alleges that the defendants acknowledged this single approved use in a pamphlet. (*Id.* at 6) Defendants, however, were allegedly determined that Sculptra would be prescribed "off-label" for cosmetic use as a "wrinkle-buster." (*Id.* at 7)

In 2007, Clements was prescribed Sculptra. (*Id.* at 8) She alleges in her brief (and her complaint) that she relied on unspecified representations that the product was safe and effective. (*Id.*) In an interrogatory response, Clements added that she "relied upon the oral representation of Dr. Marilyn Berzin," her dermatologist. (Decl. of Michael Rato in Support of Def.'s Mot. for Summ. J. ("Rato Decl."), Ex. F, Dkt. No. 9-9, at 8-9).

Sanofi confirms that Clements's dermatologists were Drs. Marilyn Berzin and Dale Isaacson. (Rato Decl., Ex. E, Dkt. No. 9-8, at 2) Sanofi attaches a consent form, dated October 26, 2007, allegedly signed by Clements. (*Id.*) That form, entitled "Informed Consent for Sculptra® Therapy," states, *inter alia*: "Sculptra therapy has been approved by the United States Food and Drug Administration (FDA) for the restoration and/or correction of facial fat loss (lipoatrophy) in people with HIV. Sculptra® therapy *has not been specifically approved by the FDA for aesthetic (cosmetic) use.*" (*Id.* at 3) (emphasis added).

Clements states in her brief that Sculptra was not approved for cosmetic use until two years after it was prescribed to her, *i.e.*, in 2009. (Dkt. No. 14, at 9).

The Present Action

Clements commenced this action on April 2, 2013, in the Superior Court of New Jersey, Essex County. The Complaint (Dkt. No. 1-2) asserts against Sanofi state-law causes of action for breach of express and implied warranty (Count I), negligence (Count II), strict liability (Count III), violations of the New Jersey Products Liability Act (Count IV), and punitive damages deriving from those violations (Count V).

Clements's complaint is virtually devoid of relevant facts. Count One, for example, recites that Sanofi is the manufacturer of Sculptra. It alleges that Clements used the product at an unspecified "aforementioned time and place." It alleges in boilerplate fashion that Sanofi "warranted, both implied and expressed, that such product was reasonably safe, fit and suitable for its intended use and reasonably foreseeable misuses and was of merchantable quality"; that she relied on those warranties; and that the Sanofi breached such warranties, causing her damage. The other counts follow the same pattern. They recite the bare legal elements of causes of action, with no supporting facts.

On March 6, 2014, Sanofi removed this action to federal court. Some limited discovery occurred. On May 29, 2014, Sanofi filed this motion for summary judgment. (Dkt. No. 9) In support, Sanofi submitted a memorandum of law; a properly supported statement of undisputed facts pursuant to Local Rule 56.1; and a declaration attaching certain exhibits, including publicly filed documents evidencing the FDA's premarket approval of Sculptra, as well as certain medical records and Clements's response to initial interrogatories. (Dkt. No. 9-3)

In response, Clements filed a memorandum of law. (Dkt. No. 14) She did not file affidavits of potential witnesses or sponsors of exhibits. Nor did she file

the statement of uncontested facts required by Local Rule 56.1. Rather, Clements's counsel attached to her brief a copy of "a 24-page pamphlet for Sculptra entitled 'Prescribing Information.'" (*Id.* at 6; *see also* Ex. A, Dkt. No. 14-3) Also attached to the brief is a copy of what appears to be an affidavit of Dr. Amy Newburger, filed in a New York state court case. (Ex. B, Dkt. No. 14-3) Newburger's affidavit states, *inter alia,* that a Sanofi sales person promoted Sculptra to her off-label as a "wrinkle-filler." Dr. Newburger, however, is not alleged to have ever treated Clements, the plaintiff in *this* case.

Sanofi filed a reply memorandum of law. (Dkt. No. 16) It later filed supplemental letters alerting the court to recently-decided opinions in Sculptra-related cases. (Dkt. Nos. 19, 21)

Sanofi filed a motion to stay discovery on the same day it moved for summary judgment. (Dkt. No. 10) On July 15, 2014, Clements agreed to the stay of discovery pending resolution of the summary judgment motion. (Dkt. Nos. 12, 13)

II. JURISDICTION

This Court has subject matter jurisdiction over this case pursuant to 28 U.S.C. § 1332(a), as there is complete diversity of citizenship between the parties and the amount in controversy exceeds $75,000.

III. GOVERNING STANDARDS

A. Summary Judgment

Sanofi has moved for summary judgment pursuant to Federal Rule of Civil Procedure 56. Rule 56(a) provides that summary judgment should be granted "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(a); *see also Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). If the moving party meets its threshold burden, the opposing party

must present actual evidence that creates a genuine issue as to a material fact for trial. *Anderson*, 477 U.S. at 248; *see also* FED. R. CIV. P. 56(c) (setting forth types of evidence on which nonmoving party must rely to support its assertion that genuine issues of material fact exist).

Where the factual record is not developed, Rule 56(d) permits the party opposing summary judgment to "show by affidavit or declaration that, for specified reasons, it cannot present facts essential to justify its opposition." In such a case, the court may "(1) defer considering the motion or deny it; (2) allow time to obtain affidavits or declarations or to take discovery; or (3) issue any other appropriate order." *See* FED. R. CIV. P. 56(d). The opposing party's affidavit or declaration "must identify with specificity what particular information is sought; how, if uncovered, it would preclude summary judgment, and why it has not been previously obtained." *Lunderstadt v. Colafella*, 885 F.2d 66, 71 (3d Cir. 1989) (internal quotation omitted). "[B]are conclusions or mere conjecture regarding facts that *may* be uncovered through discovery" are insufficient. *New Cmty. Corp. v. Arthur J. Gallagher Risk Mgmt. Servs., Inc.*, 2011 WL 4020941, *3 (D.N.J. Sept. 9, 2011), *report and recommendation adopted,* 2011 WL 1594293 (D.N.J. Sept. 30, 2011).

Clements, faced by a motion for summary judgment, has failed to comply with federal procedures. She has not submitted any affidavit properly establishing the genuineness of exhibits; she merely attaches them to her brief. She has not submitted the responsive Statement of Material Facts Not in Dispute required by Local Rule 56.1(a).[3] Although she claims that she needs more discovery, she has not filed a Rule 56(d) affidavit. That was a risky omission. Except in rare cases, "failure to comply with [Rule 56(d)] is fatal to a

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[3] Local Rule 56.1 states: "The opponent of summary judgment shall furnish, with its opposition papers, a responsive statement of material facts, addressing each paragraph of the movant's statement, indicating agreement or disagreement and, if not agreed, stating each material fact in dispute and citing to the affidavits and other documents submitted in connection with the motion."

claim of insufficient discovery on appeal." *Bradley v. United States*, 299 F.3d 197, 207 (3d Cir. 2002); *see also LaBarre v. Bristol-Myers Squibb Co.*, 544 F. App'x 120, 124 (3d Cir. 2013) ("Because [the plaintiff] did not submit a Rule 56(d) affidavit requesting additional time to obtain [discovery], the District Court ha[s] no reason to lift the discovery stay or withhold deciding the summary judgment motion based on a potential need for [such discovery]"); *Dowling v. City of Phila.*, 855 F.2d 136, 139–40 (3d Cir.1988). It is true, however, that Sanofi filed its summary judgment motion very early in the case, when there had been only minimal discovery.[4]

Plaintiff did not choose this federal forum, and I will be lenient in this instance, relaxing the Federal Rules of Civil Procedure to achieve substantial justice under the circumstances. *See generally* FED. R. CIV. P. 1 (rules "should be construed and administered to secure the just, speedy, and inexpensive determination of every action and proceeding."). Clements and her counsel will be expected to comply with the rules and procedures of this court going forward. Nevertheless, for the reasons stated at pp. 1-2, above, I have determined that the fairest procedure is to treat Sanofi's motion as a motion to dismiss the complaint.

B. Motion to Dismiss

Rule 12(b)(6), Fed. R. Civ. P., provides for the dismissal of a complaint, in whole or in part, if it fails to state a claim upon which relief can be granted. The defendant, as the moving party, bears the burden of showing that no claim has been stated. *Animal Science Products, Inc. v. China Minmetals Corp.*, 654

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[4] Sanofi removed this action to federal court on March 6, 2014. On March 27, 2014, Clements proposed a joint discovery plan. (Dkt. No. 8) On March 29, 2014, Sanofi simultaneously moved for summary judgment and to stay discovery pending the resolution of its summary judgment motion. On June 6, 2014, then-Magistrate Judge Madeline Arleo entered a scheduling order directing the parties to complete fact discovery by February 28, 2015. On July 14, 2014, Clements stipulated to Sanofi's motion to stay discovery pending resolution of the summary judgment motion.

F.3d 462, 469 n. 9 (3d Cir. 2011). For the purposes of a motion to dismiss, the facts alleged in the complaint are accepted as true and all reasonable inferences are drawn in favor of the plaintiff. *New Jersey Carpenters & the Trustees Thereof v. Tishman Const. Corp. of New Jersey*, 760 F.3d 297, 302 (3d Cir. 2014).

Federal Rule of Procedure 8(a) does not require that a complaint contain detailed factual allegations. Nevertheless, "a plaintiff's obligation to provide the 'grounds' of his 'entitlement to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). Thus, the complaint's factual allegations must be sufficient to raise a plaintiff's right to relief above a speculative level, so that a claim is "plausible on its face." *Id.* at 570; *see also Umland v. PLANCO Fin. Serv., Inc.*, 542 F.3d 59, 64 (3d Cir. 2008). That facial-plausibility standard is met "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Twombly*, 550 U.S. at 556). While "[t]he plausibility standard is not akin to a 'probability requirement' . . . it asks for more than a sheer possibility." *Iqbal*, 556 U.S. at 678.

When deciding a motion to dismiss, a court may consider facts appropriate for judicial notice without converting the motion into a motion for summary judgment. *See Pension Ben. Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196 (3d Cir. 1993) ("We now hold that a court may consider an undisputedly authentic document that a defendant attaches as an exhibit to a motion to dismiss if the plaintiff's claims are based on the document."); *In re Wellbutrin SR/Zyban Antitrust Litig.*, 281 F. Supp. 2d 751, 755 n.2 (E.D. Pa. 2003) (taking notice of and considering reports published on the FDA's website in addition the facts alleged in the complaint).

IV. ANALYSIS

Sanofi argues that Clements's claims are either subsumed under the New Jersey Products Liability Act ("PLA"), N.J.S.A. § 2A:58C-2, or preempted in their entirety by the MDA, as interpreted by the Supreme Court in *Riegel*, 552 U.S. at 330. Clements does not address the PLA argument, but contends that certain existing or potential claims are not preempted by the MDA because they are valid "parallel claims" under *Riegel*'s preemption regime.

A. Subsumption by the Products Liability Act

As an initial matter, Clements's claims for breach of implied warranty (Count I), negligence (Count II), and strict liability (Count III) are subsumed by the PLA. Because they do not constitute viable separate claims under New Jersey law, they must be dismissed as a matter of law.

The PLA "established the sole method to prosecute a product liability action" such that "only a single product liability action remains." *Tirrell v. Navistar Int'l, Inc.*, 248 N.J. Super. 390, 398–99 (App. Div. 1991). "The language chosen by the Legislature in enacting the PLA is both expansive and inclusive, encompassing virtually all possible causes of action relating to harms caused by consumer and other products." *In re Lead Paint Litig.*, 191 N.J. 405, 436–47 (2007). It "effectively creates an exclusive statutory cause of action for claims falling within its purview." *Repola v. Morbark Indus., Inc.*, 934 F.2d 483, 492 (3d Cir. 1991). It subsumes any cause of action "for harm caused by a product, irrespective of the theory underlying the claim, except actions for harm caused by breach of an express warranty." N.J.S.A. § 2A:58C–1(b)(3). In short, those former common-law causes of action (with the exception of breach of express warranty) have merged into a single cause of action under the PLA.

Thus New Jersey law no longer recognizes breach of implied warranty, negligence, and strict liability as viable separate claims for harm deriving from a defective product. Recognizing as much, the Third Circuit, this district court,

and the state courts of New Jersey have consistently dismissed product liability claims based on those common-law theories.[5]

I follow suit. Count I (to the extent it alleges breach of implied warranty),[6] Count II, and Count III will be dismissed as matter of law.

B. Preemption Under the MDA

I next focus on Count IV (PLA claim), and Count V (derivative claim for punitive damages). Because those claims are preempted by federal law, they will be dismissed.

1. *Riegel*'s Preemption Regime

Section 360k(a) of the MDA contains an express preemption provision:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

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[5] *See, e.g., Port Auth. of N.Y. & N.J. v. Arcadian Corp.*, 189 F.3d 305, 313 (3d Cir. 1999) (dismissing negligence claim, stating that "[u]nder New Jersey law negligence is no longer viable as a separate claim for harm caused by a product"); *Repola*, 934 F.2d at 489–94 (dismissing claims of negligence and negligent failure to warn); *Thomas v. Ford Motor Co.*, 70 F. Supp. 2d 521, 528–29 (D.N.J. 1999) (dismissing common-law claim for negligent manufacture); *Reiff v. Convergent Techs.*, 957 F. Supp. 573, 583 (D.N.J. 1997) (dismissing negligence and breach of warranty claims); *McWilliams v. Yamaha Motor Corp. USA*, 780 F. Supp. 251, 262 (D.N.J. 1991) (dismissing claims of negligence and breach of implied warranty), *aff'd in part, rev'd in part on other grounds*, 987 F.2d 200 (3d Cir. 1993); *Tirrell*, 248 N.J. Super. at 399 (dismissing negligence claim); *see also, e.g., Green v. Gen. Motors Corp.*, 310 N.J. Super. 507, 517 (App. Div. 1998) (stating that "causes of action for negligence, strict liability and implied warranty have been consolidated into a single product liability cause of action" under the PLA); *Ramos v. Silent Hoist & Crane Co.*, 256 N.J. Super. 467, 473 (App. Div. 1992) (stating that "Legislature has consolidated the negligence, breach of warranty and strict liability theories for product liability claims" into single product liability action under PLA).

[6] Count I's claim of breach of *express* warranty is addressed in Section IV.C., *infra*.

> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

In *Riegel*, the Supreme Court set forth a two-step analysis for courts to determine whether the MDA expressly preempts a state law claim within the meaning of § 360k(a). First, a court must determine whether the FDA has established "requirements"—the term used in § 360k(a)— applicable to the particular medical device at issue. 552 U.S. at 321. If it has, then the second step requires a court to determine whether the state law claims in question are based on state "requirements" that "relate to the safety or effectiveness of the device" *and* are "different from, or in addition to" the federal requirements. *Id.* at 321-22.

Riegel concluded that the first prong of the preemption test is automatically satisfied where a medical device has received premarket approval. *Id.* at 321-23. The PMA process necessarily imposes federal requirements, the Court found, because the FDA requires that a medical device be "made with almost no deviations from the specifications in [the PMA] application." *Id.* at 323. Turning to state law, the Court considered whether common law tort claims for negligence, strict liability, and breach of warranty establish requirements, and, if so, whether those requirements are "different from, or in addition to" the federal PMA requirements. *Id.* at 323. The Court answered yes. It reasoned that safety and effectiveness are "the very subjects" of such tort causes of action. *Id.* Thus, the Court held, those duties imposed by common law must be regarded as state law requirements. *Id.* at 324. And those state tort-based requirements of safety and effectiveness implicate the core concerns of the federal PMA process.

The upshot of *Riegel*, then, is that the MDA preempts state tort claims to the extent that they would impose requirements on device manufacturers that

deviate from those imposed by federal law—particularly, those imposed in the PMA process. Accordingly, courts within the Third Circuit have consistently held that tort claims based on negligence, manufacturing and design defects, strict liability, breach of warranty, and failure to warn, including such claims as subsumed by the New Jersey PLA, are preempted by MDA.[7]

Not *all* state law claims, however, are expressly preempted by the MDA. *Riegel* left the door ajar for a narrow category of state law claims that "parallel," rather than add to, federal requirements. *Id.* at 330. Such parallel claims must show a link between a specific violation of an FDA regulation and the plaintiff's injury. *See Smith v. Depuy Othropaedics, Inc.*, 2013 WL 1108555, at *12 (D.N.J. Mar. 18, 2013) ("State claims 'premised on a violation of FDA regulations,' however, are parallel to federal requirements, and thus, are not preempted.") (quoting *Riegel*, 552 U.S. at 330) The parallel claim exception to preemption, however, requires more than just a change of terminology; a plaintiff "cannot simply incant the magic words '[Defendant] violated FDA regulations' in order to avoid preemption." *In re Medtronic*, 592 F. Supp. 2d 1147, 1158 (D. Minn. 2009); *see also Smith*, 2013 WL 1108555, at *12 ("[B]road references to federal regulations in pleadings are insufficient" to properly plead a parallel claim) (citations omitted). Rather, the plaintiff must plead "facts showing action or

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[7] *See, e.g., Williams v. Cyberonics, Inc.*, 388 F. App'x 169, 171 (3d Cir. 2010) ("Appellant's allegations of strict products liability based on manufacturing defect and breach of warranty are preempted by the MDA"); *Millman v. Medtronic*, 2015 WL 778779, *6 (D.N.J. Fed. 24, 2015) (holding that common law fraud, strict liability, failure to warn, breach of warranty, design defect, and manufacturing defect claims "are all preempted because they...seek to impose additional requirements"); *Desai v. Sorin CRM USA, Inc.*, 2013 WL 163298, at *4–*6 (D.N.J. Jan. 15, 2013) (finding that the plaintiffs' claims under the PLA were preempted); *Gross v. Stryker*, 858 F. Supp. 2d 466, 490 (W.D. Pa. 2012) (stating that breach of implied warranty is a state claim "that imposes requirements that are different [from], or in addition to, specific federal requirements"); *Betzley v. Medtronic, Inc.*, 827 F. Supp. 2d 443, 453 (E.D. Pa. 2011) (deciding that design defect claims are preempted); *Hayes v. Howmedica Osteonics Corp.*, 2009 WL 6841859, at *6 (D.N.J. Dec. 15, 2009) (finding that a failure to warn claim is preempted); *Delaney v. Stryker Orthopaedics*, 2009 WL 564243, at *3 (D.N.J. Mar. 5, 2009) (holding that "the MDA preempts products liability claims, including" failure to warn, defective design, negligence and breach of implied warranty).

inaction in [the] defendants' efforts to take part in the PMA process or implement its results." *Smith*, 2013 WL 1108555, at *12 (citations omitted). In short, a "parallel claim," like any other, is subject to the pleading standards of *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007)

2. Application to Counts IV and V of the Complaint

Counts IV and V of the Complaint are premised upon violations of the PLA. Count IV alleges that Sanofi violated the PLA because Sculptra's design and manufacture were defective and its warnings inadequate. Count V seeks punitive damages for the harm allegedly caused by the PLA violations. From the face of the complaint, it is apparent that these counts, at least as currently alleged, are preempted by the MDA and thus should be dismissed as a matter of law.[8]

Since Sculptra was cleared for sale through the PMA process, it is subject to federal requirements within the meaning of § 360k(a) of the MDA. *See Riegel*, 552 U.S. at 322 ("Premarket approval...imposes 'requirements' under the MDA). By approving Sanofi's PMA application, the FDA determined that Sculptra's manufacture, design, and warnings were safe and effective.

Under the PLA , a "manufacturer or seller of a product" is liable:

> [O]nly if the claimant proves by a preponderance of the evidence that the product causing the harm was not reasonably fit, suitable or safe for its intended purpose because it: a. deviated from the design specifications, formulae, or performance standards of the manufacturer or from otherwise identical units manufactured to the same manufacturing specifications or formulae, or b. failed to

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[8] Because preemption may often be determined from the face of the complaint, "many PMA preemption motions are decided without any discovery." *Smith v. Depuy Orthopaedics Inc.*, 552 F. App'x 192, 196 (3d Cir. 2014) (citing *Bass v. Stryker Corp,* 669 F.3d 501, 508 n. 1 (5th Cir. 2012); *Gross v. Stryker, Corp.* 858 F.Supp.2d 466, 505 (W.D. Pa. 2012); *Lewkut v. Stryker Corp.*, 724 F.Supp.2d 648, 653 n. 1 (S.D. Tex. 2010) ; *Desai v. Sorin CRM USA, Inc.*, 2013 WL 163298, at *9 (D.N.J. Jan. 15, 2013); *Hayes v. Howmedica Osteonics Corp.*, 2009 WL 6841859, at * 6–8 (D.N.J. Dec. 15, 2009); *Delaney v. Stryker Orthopaedics,* 2009 WL 564243, at *4 (D.N.J. Mar. 5, 2009)).

> contain adequate warnings or instructions, or c. was designed in a defective manner.

N.J.S.A. 2A:58C-2.

> The PLA further provides:
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> [A] manufacturer or seller shall not be liable for harm caused by a failure to warn if the product contains an adequate warning or instruction or, in the case of dangers a manufacturer or seller discovers or reasonably should discover after the product leaves its control, if the manufacturer or seller provides an adequate warning or instruction.

N.J.S.A. 2A:58C–4.

Under the PLA, then, a manufacturer is liable "only if the claimant proves that the device was not reasonably fit, suitable or safe for its intended purpose because it deviated from design specifications." *Smith v. Depuy Orthopaedics, Inc.*, 2013 WL 1108555, at *9 (D.N.J. Mar. 18, 2013) *aff'd in part*, 552 F. App'x 192 (3d Cir. 2014). However, by granting PMA, the FDA determined that Sculptra's manufacture, design, and warnings *were* safe and effective. To subject Sanofi to liability under the PLA would thus impose requirements regarding the safety and effectiveness of Sculptra that are "different from, or in addition to" the federal requirements. *See, e.g.*, *Desai*, 2013 WL 163298, at *4–6 (finding that the plaintiff's PLA claims were preempted). As a result, Count IV and the derivative claim for punitive damages under Count V are preempted under § 360k(a).

As set forth above, there is a narrow exception for a "parallel" claim, *e.g.*, "a damages remedy for claims premised on a violation of FDA regulations." *Riegel*, 552 U.S. at 330. But nowhere in her Complaint does Clements even purport to set forth any allegation of a violation of a federal standard. Therefore, Counts IV and V, as pled, cannot escape preemption under *Riegel*'s parallel claims exception. Accordingly, the claims are preempted as a matter of law and must be dismissed.

3. "Off-Label" Promotion

In her moving papers, Clements attempts to salvage Counts II, IV, and V from preemption by depicting them as "parallel" claims based on Sanofi's alleged off-label promotion of Sculptra. (Pl.'s Mem. of Law in Opp'n to Corp. Defs.' Mot. for Summ. J. ("Pl.'s Opp'n"), Dkt. No. 14, 22-33) Her brief argues that, even though Sculptra had not been approved for cosmetic use at the time she received her injection, Sanofi engaged in an "off-label usage advertising campaign" to promote the use of Sculptra for cosmetic purposes. (*Id.* at 22) This promotional activity, she asserts, violated several provisions of the Food, Drug, and Cosmetics Act (FDCA) (21 U.S.C. § 331(a), (g), (k) and (n), and 21 U.S.C. 352 (f), (n), and (q)0, as well as a related federal regulation (21 C.F.R. 801.4). Taken together, those cited provisions list certain conditions under which a medical device may be deemed "misbranded" within the meaning of the FDCA, and prohibit the manufacture, sale and marketing of any such "misbranded" device.

Clements claims that the duties imposed by state law under Counts II, IV, and V parallel the duties imposed by the federal misbranding provisions. Therefore, she says, her claims under those counts would be valid, parallel claims which are not preempted by the MDA. There are at least three problems with that contention.

First, Count II, the negligence claim, is still invalid as a matter of law. Because it is subsumed by the PLA, it fails to state a valid claim under New Jersey state law, irrespective of whether it is preempted by federal law.

Second, Counts IV and V, to the extent they are intended to state parallel, "off label" claims, fail to meet the minimal pleading standards of Fed. R. Civ. P. 8(a) and *Twombly*. *See* pp. 9-10, *supra*. Those counts, in boilerplate fashion, recite the legal elements of a PLA claim and a derivative claim for

punitive damages. Thus, Count IV alleges that Sanofi marketed a product that was not "reasonably fit, suitable or safe for its intended purpose because it: a) deviated from the design specifications, formulae or performance standards of the manufacturer or from otherwise identical units manufactured to the same manufacturing specifications or formulae and/or b) failed to contain adequate warnings or instructions, and/or c) was designed in a defective manner." No supporting facts are pled. Counts IV and V say literally nothing about any off-label promotional campaign. They do not cite 21 U.S.C. § 331(a), (g), (k) and (n), 21 U.S.C. 352 (f), (n), and (q), or 21 C.F.R. 801.4. And the Complaint contains no facts from which the reader could conclude that Sculptra's manufacture, design, warnings, or alleged off-label promotion actually violated any of the federal provisions Clements cites in her brief.

Counts IV and V embody the kind of conclusory recitals of legal elements, unsupported by factual allegations, that are barred by *Twombly*. Parallel claims, like others, must contain more than "labels and conclusions." *Twombly*, 550 U.S. at 555; *see also Parker v. Stryker Corp.*, 584 F. Supp. 2d 1298, 1301 (D. Colo. 2008) (conclusory allegations are insufficient to state a parallel claim). Clements does not plead facts which, if proven, would link any alleged violation of federal standards to her injury. *See Purcel v. Advanced Bionics*, 2008 WL 3874713, *1 (N.D. Tex. Aug. 13, 2008) (plaintiff successfully stated a parallel by alleging that a supplier's modification of a component part of the regulated device at issue caused the injury). And inadequate factual allegations in a complaint are not remedied by statements in the plaintiff's briefs. *See, e.g., Zimmerman v. PepsiCo, Inc.*, 836 F.2d 173, 181 (3d Cir. 1988) ("It is axiomatic that the complaint may not be amended by the briefs in opposition to a motion to dismiss.") (citation omitted). Counts IV and V must be dismissed, albeit without prejudice, for the reasons expressed above.

For Clements's guidance in drafting any amended complaint, I point out a third potential flaw. An off-label promotion theory may fail to state a cause of

action to the extent that it illegitimately shifts the risk of off-label use from prescribing doctors and patients to manufacturers. Congress spoke directly to off-label use in 21 U.S.C. § 396. There, as the Tenth Circuit Court of Appeals recently stated, the legislators went out of their way "to protect the liberty of doctors and patients to use approved devices in any manner they wish—including off-label—instructing that '[n]othing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device." *Calpinger v. Mediatronic, Inc.*, 2015 WL 1786742, at *9 (10th Cir. Apr. 21, 2015) (quoting 21 U.S.C. § 396). In protecting this liberty to use approved devices off-label, Congress appeared to intentionally place "a good deal of the risk on [doctors and patients] rather than on manufacturers." *Id.* Indeed, as the Tenth Circuit points out, despite acknowledging—and perhaps even tacitly encouraging—off-label usage in § 396, Congress nonetheless proceeded to enact the robust the preemption provision found in §360k(a). "Given that Congress well understood the difference between on- and off-label uses and exhibited its facility with those terms in § 396, the absence of any mention of them in § 360k(a) becomes all the harder to ignore[.]" *Id.*

Nothing in § 360k(a) suggests that the preemption analysis somehow depends on *how* the device in question is being used. *See, e.g., Calpinger v. Medtronic, Inc.*, 921 F. Supp. 2d 1206, 1215 (W.D. Okla. 2013) ("plaintiff's off-label promotion allegations do not somehow turn [her] claims into parallel claims.") A hypothetical claim (not pled in the current complaint) that Sanofi's design, manufacture, or warnings were defective because they ignored the possibility that doctors would prescribe Sculptra for off-label cosmetic use, would not necessarily constitute a non-preempted, "parallel" state-law claim. It might well constitute a state law requirement that is expressly preempted by § 360k(a). An allegation that a product's warnings were inadequate, for example, may be tantamount to a requirement that Sanofi must do something "different from, or in addition to" what the FDA had already approved. *See Thron v.*

Medtronic Sofamor Danek, USA, Inc., 2015 WL 328885 at *7 (W.D. Mich. Jan. 23 2015). That is to say, "a jury would have to find either that Defendants were required to include warnings beyond those in the FDA-approved label...or that Defendants were obligated to issue post-sale warnings about potential adverse effects of using [the product] in an off-label manner." *Id.* (internal quotations omitted). As I say, I do not prejudge the matter, but state these principles for Clements's guidance in drafting any amended complaint.

Counts II, IV and V fail to state a cause of action and must be dismissed; under established pleading standards, they cannot be saved by Clements's allegations and arguments in her brief. Any amended pleading, moreover, should take into account the standards of law stated above.

C. Express Warranty

What remains of the Complaint, then, is Count I, to the extent it pleads a breach of express warranty. Unlike other claims in the complaint, the express warranty claim is not subsumed by the PLA. *See* N.J.S.A. 2A:58C-1b(3). Likewise, an express warranty claim is not necessarily preempted under the MDA—at least not if the plaintiff can show that the defendant-manufacturer made "voluntary statements" that were "not approved by the FDA or mandated by the FDA about the use or effectiveness" of a medical device. *See Cornett v. Johnson & Johnson*, 211 N.J. 362, 392 (2012). I therefore consider whether the express warranty claim in Count I meets the minimal pleading standards of Fed. R. Civ. P. 8 and *Twombly*. *See* pp. 9-10, *supra*. I conclude that it does not, and that it must therefore be dismissed.

Under New Jersey law, a claim for breach of express warranty has three essential elements: "(1) that Defendant made an affirmation, promise or description about the product; (2) that this affirmation, promise or description became part of the basis of the bargain for the product; and (3) that the product ultimately did not conform to the affirmation, promise or description."

Snyder v. Farnam Companies, Inc., 792 F. Supp. 2d 712, 721 (D.N.J.2011) (citing N.J. Stat. Ann. § 12A:2–313).

Count I of the Complaint recites that Sanofi is the manufacturer of Sculptra. It alleges that Clements used the product at an unspecified "aforementioned time and place," although it is unclear what "time and place" that might refer to. Count I alleges in boilerplate fashion that the defendants "warranted, both implied and expressed, that such product was reasonably safe, fit and suitable for its intended use and reasonably foreseeable misuses and was of merchantable quality"; that the plaintiff relied; and that the defendants breached such warranties, causing her damage.

Count I asserts no supporting facts. The content of any such "warranty" is not given. Who said what to whom, where, when, and how, are left unexpressed. There is no factual allegation in the Complaint that Sanofi ever made any identifiable, unapproved statements to Clements or her physician regarding the safety, effectiveness or proper applications of Sculptra. In short, this is "a formulaic recitation of the elements of a cause of action," which *Twombly* tells us "will not do." 550 U.S. at 556.

For the reasons stated above, such allegations do not come close to meeting the federal requirement that the complaint plead facts that would plausibly support a cause of action. Count I, to the extent it asserts an express warranty claim, will be dismissed.[9]

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[9] Clements's counsel attaches to her brief a copy of an affirmation of Dr. Amy Newberger. That affirmation states that in March 2004, a sales representative from a subdivision of Sanofi "contacted [Dr. Newberger] and described [Sculptura] as a 'wrinkle filler.'" (Dkt. No. 14-3, at 3) This affirmation, executed in August 2011, seems to have been simply copied from the docket in an unrelated case in New York State court. In this case, any amended claim must allege that such an express warranty was made in connection with the medical treatment of Clements, not of someone else.

D. Dismissal Without Prejudice

Finally, I must decide whether the dismissal of the Complaint will be with or without prejudice. As noted above, Clements filed her complaint in State court, and therefore may not have given sufficient attention to federal substantive and procedural standards. Of course, even when dismissing a complaint initially filed in federal court, a court will commonly provide that such dismissal is without prejudice. The Third Circuit has liberally permitted pleading amendments to ensure that "a particular claim will be decided on the merits rather than on technicalities." *Dole v. Arco Chem. Co.*, 921 F.2d 484, 487 (3d Cir. 1990). Indeed, where a complaint is dismissed on Rule 12(b)(6) grounds, "a District Court must permit a curative amendment, unless an amendment would be inequitable or futile." *Alston v. Parker*, 363 F.3d 229, 235 (3d Cir. 2004).

There are some initial barriers to Clements's claims—most prominently, preemption. I cannot now say, however, that to give her a chance to formulate a valid complaint would be "futile." I will therefore permit the plaintiff to file an amended complaint within 30 days. Any amended complaint should conform to the standards of *Twombly* and Rule 8(a), and should take into account the substantive legal principles discussed above. Before embarking on summary judgment or a trial, it is necessary to ensure that plaintiff has filed a complaint that meets federal pleading standards and sets forth a valid legal claim.

V. CONCLUSION

For the reasons set forth above, Sanofi's motion for summary judgment is denied as presented but, considered as a motion to dismiss the complaint, is **GRANTED** without prejudice to the filing of an amended complaint within 30 days after the date of this opinion.

An appropriate order will issue.

KEVIN MCNULTY, U.S.D.J.

Date: June 10, 2015